REMARKS

Applicants appreciate the acknowledgement of their previous submissions, including an Information Disclosure Statement, and have corrected claim 7 as kindly noted by the Office and required.

Applicants further appreciate the withdrawal of the rejections previously made under sections 112, 102 and 103 as applied to claims 1-5 and 31. One rejection remains for each of the independent claims and claims dependent on each.

The Rejection of Claims 1-5 and 31

These claims were rejected as assertedly failing to comply with the written description requirement on the basis of new matter. The basis for this rejection is the amendment of claim 1 by replacing "comprises" by "consists of". Applicants believe this basis for rejection is in error.

By replacing "comprises" with "consists of", applicants have merely limited their claim to the disclosed elements. The disclosure of these elements by the applicants has not been questioned by the Office. It is therefore not seen why this would be considered new matter. By limiting the claims only to those elements whose disclosure has been acknowledged, no new matter is added, as no new element is proposed.

Applicants have been unable to find any case law specifically addressing the issue of whether substituting "consists of" for "comprises" constitutes new matter, which does not seem surprising. In 25 years of practice, applicants' undersigned representative has never encountered an objection based on this change in terminology. However, it is believed that the holding in *In re Driscoll*, 195 USPQ 434 (CCPA 1977) illustrates applicants' point. In Driscoll, a particular compound was claimed where a substituent was defined as alkyl sulfonyl (C_1-C_6). The issue was whether applicants were entitled to claim priority from a parent application which disclosed the same compound but listed a Markush group of 14 variable substituents which included alkyl sulfonyl (C_1-C_6) in the same position of the claimed compound.

The Court reversed the Board of Appeals holding that a compound which was limited to only one of the 14 substituents in this position as new matter was a "hypertechnical application" of the written description requirement of section 112. They quoted Judge Leonard Hand that in order to avoid this, a surfeit of verbiage would be required that would be counter-productive.

The Court also distinguished the holding in *In Re Ruschig*, 154 USPQ 118 (CCPA 1967) where support was not found where more than one substituent had to be varied, since the specific claimed embodiment was not unambiguously disclosed.

Respectfully, it is submitted that the present case is more similar to *In Re Driscoll* than *In Re Ruschig* and indeed, puts applicants in a stronger position since applicants are simply no longer including unnamed elements that were never in the claim in the first place. Accordingly, applicants believe the rejection of claims 1-5 and 31 as containing new matter should be withdrawn and these claims passed to allowance, as their patentability over the art has been acknowledged.

The Rejection of Claim 7 and 10-13

These claims were rejected as assertedly obvious over the combination of Katz (either WO93/13663 or U.S. 5,824,513), in combination with Kao, et al., *Science* (1992) 265:509-512.

As a preliminary matter, applicants wish to clarify that their previous remarks stating that Kao is "irrelevant to these claims" clearly refers to claims 1-5 and 31, not to claims 7 and 10-13. Applicants also have not argued that Kao does not teach homologous recombinant techniques. Obviously, Kao does teach such techniques.

Further, applicants do not understand the references made by the Office in this basis for rejection to page 6, lines 26-29 of the Katz PCT publication which state that "the correct enantiomer (2R or 2S of methylmalonyl-CoA) as the extended unit employed at each condensation is specified by the acyltransferase function determined by the module" as relevant to the present invention or to column 4, lines 16-21 as being adequate to support the rejection. In that section, "type III change" is simply defined as including "macrolide rings altered in specific portions of the chain

(replacement)". However, the previous basis for rejection did note the relevant portion of the PCT publication on page 35 at lines 17-26 as suggesting replacement of acyltransferase segments. As far as applicants can tell, however, the actual replacement of such "acyltransferase segments" was not described in either of the Katz publications.

Perhaps applicants did not make sufficiently clear the distinction between the present invention as set forth in claims 7 and 10-13 and the description of Kao.

It is correct that claim 7 describes a variant of the method described by Kao as applied to exchanging an AT segment of a polyketide synthase-encoding sequence. However, the challenges in doing so are much greater because the flanking sequences that must be used to exchange just this segment must be matched in the donor and acceptor plasmids. These regions are derived from different polyketide synthases and are assumed to be essential for the function of the synthases involved. Thus, it is required to alter the flanking sequences in the donor to match the naturally occurring flanking sequences in the recipient plasmid PKS. This is a problem not addressed by Kao since the flanking sequences in Kao are external to the functional elements of the vectors participating in the exchange. One of ordinary skill would not be motivated to employ the method of Kao to effect exchanges within a functional module of a desired PKS, even if Katz suggested that an exchange of AT regions would be desirable. It is this element of the claimed method which is not suggested by the cited art. Accordingly, applicants believe that claims 7 and 10-13 are patentable over the combination of Katz and Kao.

Conclusion

For the reasons set forth above, applicants believe claims 1-5, 7, 10-13 and 31 are in a position for allowance and passage of these claims to issue is respectfully requested.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 300622000508. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

Electronic signature: /Kate H. Murashige/
Kate H. Murashige
Registration No.: 29,959
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, California 92130-2040
(858) 720-5112